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09/394,006 09/10/99 BERGER

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EXAMINER

HM12/0821

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FORMAN, B

ART UNIT

PAPER NUMBER

1655

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/394,006

Applicant(s)

BERGER ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☐ Responsive to communication(s) filed on 09 June 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. This action is in response to papers filed 9 June 2000 in Paper No. 5 in which claim 1 was amended. All of the amendments and arguments have been thoroughly reviewed and are discussed below. The previous rejection of Claims 1-4, 6 & 13-17 under 35 USC § 102 and Claims 5, 7-12 under 35 USC § 102/103 are withdrawn in view of the amendments. New grounds for rejection are discussed.
2. Currently claims 1-17 are under prosecution

### ***Specification***

3. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### **First paragraph of 35 U.S.C. 112: New Matter**

5. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. The claims as amended are drawn to a composition for stabilizing the structure and nucleic acids of at least one cell said composition comprises of a first substance capable of precipitating or denaturing proteins and a second facilitator substance to aid in the infusion of the first substance wherein the combined concentration of said first and second substances is greater than 30% of the composition. However, the specification consistently teaches the combined concentration is 100% (page 4, lines 19-24, Examples 4 through 13). The specification does not teach the combined concentration is greater than 30% as claimed. Therefore the claims, as amended, introduce new matter not disclosed in the specification as originally filed. It is suggested that the claims be amended to replace "greater than 30%" with "100%" as recited in the originally filed specification.

**First paragraph of 35 U.S.C. 112: Written Description**

6. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims, as amended, are drawn to a composition for stabilizing the structure and nucleic acids of at least one cell. The specification teaches the claimed composition stabilizes vaginal swab samples (page 7, lines 7-9 and 24-26). Additionally, the specification teaches specific cell types found in vaginal fluid i.e. *Trichomonas vaginalis*, *Gardnerella vaginalis* and *Candida albican* and the claimed compositions' stabilization of the structure and nucleic acids in these cell types (pages 11-12, Examples 2 & 4-12). The specification suggests the composition "could be used for other biological specimens" (page 4, lines 26-29). However, the specification does not teach the composition stabilizes the structure and nucleic acids of other specimens in the very large genus of cells as claimed. The claimed cell encompasses eukaryotic cells which further encompasses plant and

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animal cells each of which further encompass numerous species and sub-species, prokaryotic cells which further encompasses bacteria which further encompasses numerous species not described in the specification. The specification fails to teach a representative number of the claimed species. The specification teaches various formulations of the claimed composition and experimental conditions using the compositions (Examples 4-12) but the specification does not teach using the claimed composition with a representative number of the claimed cell species. Therefore, the specification does not provide a written description of the claimed composition in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The courts have stated that the specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonable conclude the inventor had possession of the claimed invention see *In re Vas-Cath, Inc.* 935F2d. 1555, 1563, 19 USPQ2d 1111,1116. It is suggested that the claims be amended to claims the invention as described in the specification e.g. by inserting "in vaginal fluid" after "one cell" in line 2 of Claim 1.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 9 & 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dent et al. (Development, 1989, 105: 61-74).

Regarding Claim 1, Dent et al. disclose a composition comprising a first substance capable of precipitating proteins i.e. an alcohol and a second substance to aid in the infusion of

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the first substance wherein the combined concentration of said first and second substances is greater than 30% of said composition (page 62, right column, last paragraph, lines 6-7).

Regarding Claim 2, Dent et al. disclose the composition of Claim 1 wherein said at least one alcohol is methanol (page 62, right column, last paragraph, lines 6-7).

Regarding Claim 3, Dent et al. disclose the composition of Claim 1 wherein said second substance is DMSO (page 62, right column, last paragraph, lines 6-7).

Regarding Claim 4, Dent et al. disclose the composition of Claim 1 wherein said first substance is comprised of one alcohol i.e. methanol (page 62, right column, last paragraph, lines 6-7).

Regarding Claim 5, Dent et al. disclose the composition of Claim 1 wherein said concentrations of said first and second substances in said composition are in a ratio of 4:1 (page 62, right column, last paragraph, lines 6-7).

Regarding Claim 9, Dent et al. disclose the composition of Claim 1 wherein said first substance is methanol and said second substance is dimethyl sulfoxide (page 62, right column, last paragraph, lines 6-7).

Regarding Claim 16, Dente et al. disclose the composition where said cell is eukaryote (page 62, right column, last paragraph).

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. Claims 6,7 & 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dent et al. (Development, 1989, 105: 61-74) as applied to Claim 1 above and further in view of Bresser et al. (U.S. Patent No. 5,521,061, files 17 July 1992). Dent et al. disclose a composition comprising a first substance capable of precipitating i.e. an alcohol and a second substance to aid in the infusion of the first substance (page 62, right column, last paragraph, lines 6-7).

Regarding Claim 6, Dent et al. do not teach the composition wherein the first substance is comprised of a first alcohol and a second alcohol. However, Bresser et al. teach a similar composition wherein the first substance is comprised of a first alcohol i.e. dithiothreitol and a second alcohol i.e. polyethylene glycol (Column 9, lines 6-17).

Regarding Claim 7, Bresser et al. do not teach the composition wherein the ratio of the first and second substances are 2.5:2.5:5. However, Bresser et al. teach the composition wherein 2-20 percent of the composition is said first substance i.e. an alcohol and wherein 2-20 percent of the composition is said second substance i.e. dimethyl sulfoxide. It would have been known to one of ordinary skill in the art that the percentages taught by Bresser et al. include the 2.5:2.5:5 ratio e.g. 2%:2%:5% or 4%:4%:16% etc.

Regarding Claim 10, Bresser et al. teach the composition wherein said first substance is a precipitating agent i.e. alcohol and said second substance is dimethyl sulfoxide (Claim 54, lines 1-3). It was known to one of skill in the art at the time the claimed invention was made that ethanol and methanol are precipitating agents as taught by Bresser et al. (Column 7, line 40).

It would have been *prime facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Dent et al. with the teaching of Bresser et al. to obtain the claimed invention because one of ordinary skill in the art would have been motivated with a reasonable expectation of success to modify the alcohol in the composition of Dent et al. with the specific teaching of Bresser et al. wherein the alcohol is selected from the group consisting of ethanol and methanol to use ethanol and methanol in the composition at

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the ratio of 2.5:2.5:5 based on cell type being assayed, available reagents and known precipitating properties.

11. Claims 8 & 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dent et al. (Development, 1989, 105: 61-74) as applied to Claim 1 above and further in view of Bresser et al. (U.S. Patent No. 5,521,061, filed 17 July 1992). Dent et al. disclose a composition comprising a first substance capable of precipitating i.e. an alcohol and a second substance to aid in the infusion of the first substance (page 62, right column, last paragraph, lines 6-7).

Regarding Claim 8, Dent et al. do not teach a 1:1 ratio of said first and second substance. However, Bresser et al. teach a similar composition wherein 2-20 percent of the composition is said first substance i.e. an alcohol and wherein 2-20 percent of the composition is said second substance i.e. dimethyl sulfoxide. It would have been known to one of ordinary skill in the art that the percentages taught by Bresser et al. include the 1:1 ratio.

Regarding Claim 12, Dent et al. teach the composition wherein said first substance is methanol and said second substance is dimethyl sulfoxide (page 62, right column, last paragraph, lines 6-7).

It would have been *prime facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Dent et al. with the teaching of Bresser et al to obtain the claimed invention because the skilled practitioner would have been motivated with a reasonable expectation of success to modify the methanol to dimethyl sulfoxide ratio of Dent et al. based on the range of concentration percentages taught by Bresser et al. for the obvious benefit of optimizing experimental conditions to maximize experimental results. It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.



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12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dent et al. (Development, 1989, 105: 61-74) as applied to Claims 1 & 5 above. Dent et al. disclose a composition comprising a first substance capable of precipitating proteins i.e. an alcohol (page 62, right column, last paragraph, lines 6-7). Dent et al. teach the alcohol is methanol (page 62, right column, last paragraph, lines 6-7) but they do not teach the alcohol is ethanol. However, it was known in the art at the time the claimed invention was made that methanol and ethanol were homologues having similar precipitating properties. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Dent et al. with the known methanol homologous to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to use methanol and/or ethanol in the composition Dent et al. based on their known similarities and based on available reagents.

13. Claims 13-15 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dent et al. (Development, 1989, 105: 61-74) as applied to Claim 1 above and further in view of Bresser et al. (U.S. Patent No. 5,521,061, files 17 July 1992). Dent et al. disclose a composition comprising a first substance capable of precipitating proteins i.e. an alcohol and a second substance to aid in the infusion of the first substance (page 62, right column, last paragraph, lines 6-7).

Regarding Claim 13, Dent et al. do not teach the composition is effective to stabilize nucleic acids. However, Bresser et al. teach a similar composition wherein the composition is effective to stabilize nucleic acids and the nucleic acid is DNA (Column 7, lines 32-34 and Column 6, line 45).

Regarding Claim 14, Bresser et al. teach the nucleic acid is RNA (Column 7, lines 32-34 and Column 6, line 47-48).

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Regarding Claim 15, Bresser et al. teach the nucleic acid is ribosomal RNA (Column 7, lines 32-34 and Column 6, line 48).

Regarding Claim 17, Bresser et al. teach the cell is a microorganism (Column 6, line 17).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Dent et al. with the teachings of Bresser et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to apply the stabilizing properties of the Dent et al. composition to nucleic acids based on the composition of Bresser et al. comprising similar precipitating and infusion agents for the expected benefit of analyzing cells at the nucleic acid and/or protein levels as taught by Bresser et al. (Column 1, lines 35-37). The skilled practitioner would have been further motivated to apply the composition of Dent et al. to the stabilization of microorganisms as taught by Bresser et al. for the obvious benefit of analyzing cells having clinical importance.

#### **Response to Arguments**

14. Applicant argues that Bresser et al. do not teach, disclose or anticipate the claimed invention but in fact teach away from the claimed invention as amended. This argument is mooted in view of the amendments and new grounds for rejection.

Applicant argues that Bresser et al. does not teach every element of the claims as amended. The argument is mooted because the previous rejections under 35 U.S.C. § 102(b) have been withdrawn in view of the amendments.

Applicant argues that Claims 5 and 8-12 are not obvious over Bresser et al. in view of the amendments. This argument is mooted in view of the amendments and new grounds for rejection.

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15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


#### **Conclusion**

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
BJ Forman, Ph.D.  
August 16, 2000

  
Gary Jones